

EXHIBIT 15



Abt Associates Inc.

Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices

Final Report

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1.0 Introduction and Background

In both the Medicaid and the Medicare Part B prescription drug programs, there is a need for a payment methodology that accurately reflects the costs of products and services from efficient providers. One essential component of any drug payment methodology is payment for the costs of acquiring the drug product. Many state Medicaid programs and the Medicare Part B program currently base their prescription drug payment on the term known as average wholesale price (AWP), a list price from manufacturers. Other state Medicaid programs pay based on an amount labeled as wholesale acquisition costs (WAC), also a list price. However, both AWP and WAC are list prices, not transaction prices, and are widely viewed as inflated relative to actual acquisition costs.

This report provides background on current Medicaid and Medicare policy and the structure of the pharmaceutical marketplace and of pharmaceutical prices and payments, highlighting implications for the estimation of acquisition costs and for payment policy. Alternative approaches for estimating pharmacies' and physicians' acquisition costs for prescription drugs are then described and evaluated. After review and evaluation of the options, the authors recommend that actual acquisition costs be estimated by using manufacturer-supplied data on average selling prices by class of trade. The proposed approach would be similar to that used by the Texas Medicaid Vendor Drug program, but might incorporate more precise definition of terms, more classes of trade, and other differences. Given that additional primary data collection may not be efficient or feasible at this time, the authors propose to further analyze the Texas program and the data it collects in order to refine our recommended approach and to understand its potential value to public payers, either as a point of comparison for existing payment policies or as the basis of a new policy.

This report is based on the authors' experience, research, and analysis. In addition, it is based on the experience and insights of an expert panel. These 15 experts and one observer were selected in consultation with CMS to provide a range of perspectives. Experts came from a variety of sectors including CMS, vendors of drug utilization and pricing information, the pharmacy sector, oncologists and other physicians, researchers, the State Medicaid sector, drug wholesalers, and individuals with expertise in drug pricing gained via participation in, and observation of the current drug pricing environment. Appendix A lists the panel members. Each member of the panel was interviewed individually in November 2003 and attended a one and a half day panel meeting in January 2004. After the meeting, panel members were invited to further comment on key topics either in writing or by phone. Of the 15 panel members, 12 chose to provide additional comments. Themes from the panel meeting and the individual interviews are incorporated into the discussion below. Appendix B offers a summary of key points made during the January meeting.

2.0 Overview of Recent Drug Pricing Issues and Current Medicaid and Medicare Policy

2.1 Overview of Recent Drug Pricing Issues

Several essential contextual issues have implications for estimating acquisition costs in the Medicaid and Medicare context.

- Why are there concerns about drug prices and expenditures in these programs?
- What are the sources of growth in drug prices and expenditures?

- How does drug product payment fit into the total compensation to pharmacies, physicians and other providers?
- What is the structure of the pharmaceutical market both in terms of the flow of product (channels of distribution) and in terms of the flow of funds (sources of payment)?
- What are the meanings of various drug product pricing terms and how are these prices set in the market?
- Do pricing patterns differ by class of trade or type of provider (e.g., community pharmacies versus physicians versus others)?
- Do pricing patterns differ by type of drug (e.g., brand versus generic)?

Each of these issues is addressed in later portions of this report, and each bears on the appropriate method for estimating actual acquisition costs.

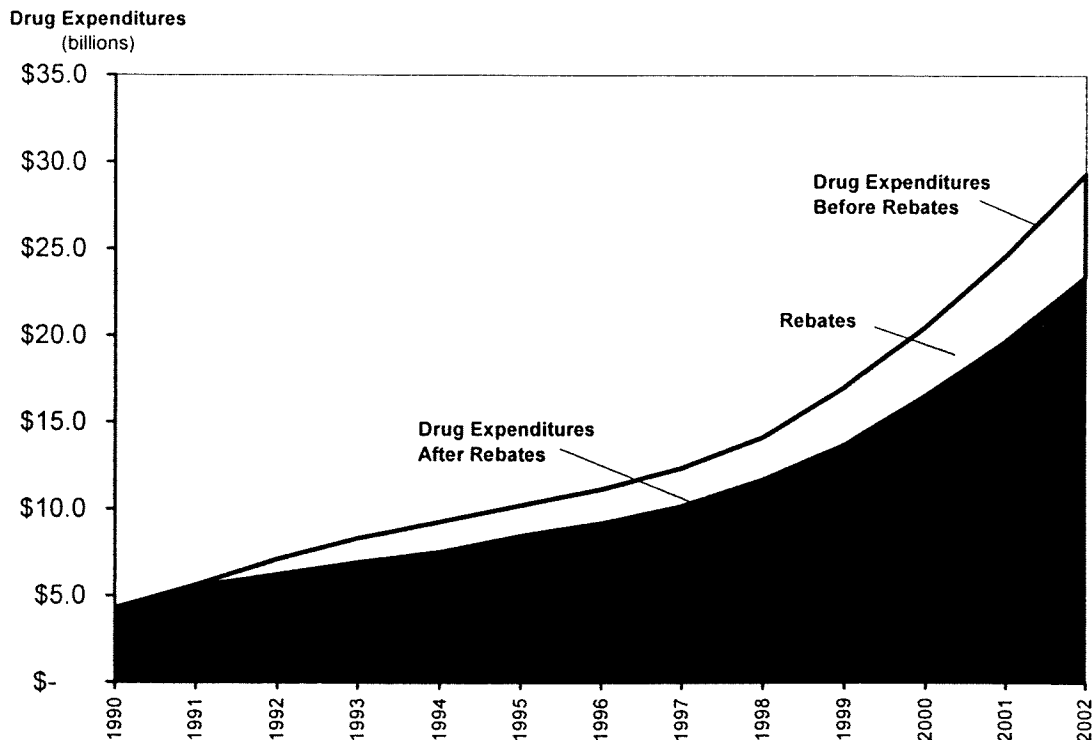
2.2 Signals of a Need for Change

A number of signals in the market have raised concern about prescription drug prices and expenditures to the top of the public policy agenda. First, outpatient drug expenditures in both public and private programs have been growing at an annual rate of 15 to 20 percent since the mid-1990s—a rate that is more than double the rate of growth in total health spending (i.e., Medicaid total expenditures grew 7.7 percent per year from 1997 to 2000).¹ Second, prescription drugs are the fastest growing sector of Medicaid programs, which, in turn, are one of the largest segments of state spending at a time when states are facing record deficits.² Third, the prices paid for prescription drugs by the Medicaid and Medicare programs have come under question compared to the prices paid by other sectors of the market.³ For example, most other government programs (i.e., the Veterans Administration, and the 340B program for federally qualified facilities) pay less for prescription drugs than do the Medicaid or Medicare Part B programs, even after accounting for rebates.⁴ Fourth, there is evidence that drug manufacturers have ‘gamed’ the pricing policies of both Medicare Part B and the Medicaid drug rebate program in a manner that creates economic incentives that lead to increased rather than decreased drug expenditures.^{5,6,7} Fifth, legislation to cover outpatient prescription drugs under Medicare has recently been passed by the U.S. Congress and is set for an ambitious implementation schedule over the next year and one-half.⁸

2.3 Medicaid Drug Program and Expenditures

The Medicaid drug program grew from \$7.1 billion in 1992 to \$29.3 billion in 2002—more than a four-fold increase in ten years (see Exhibit 1). Even after accounting for the rebates received by the Medicaid program (federal and state levels), the drug expenditures grew from \$6.2 billion to \$23.4 billion—still nearly a four-fold increase over ten years. Both legislative changes and specific trends within the drug program have contributed to the growth in drug program expenditures.

**Exhibit 1: U.S. Medicaid Drug Expenditures Before and After Rebates:
1990 to 2002 (Current \$)**



SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in CMS/HCFR-2002 Reports (adjudicated & paid claims), CMS/HCFR-64 Reports (budgeted and expended funds), CMS/HCFR Medicaid Drug Utilization public use files, and the annual volumes of Pharmaceutical Benefits Under State Medical Assistance Programs (Reston, VA: National Pharmaceutical Council, 1990 to 2002).

Legislative and Regulatory History

Historically, the Medicaid drug program has been guided by legislation and regulation that encouraged states to base their payments for the drug product cost on the concept of 'estimated acquisition cost' (EAC). A HCFA memo from 1977 described that "The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."⁹ More recent reports on the Medicaid drug program describe 'Actual Acquisition Cost' (AAC) as "the pharmacist's net payment made to purchase a drug product, after taking into account such items as purchasing allowances, discounts, rebates, and the like."¹⁰ Since the early 1980s state Medicaid programs have based their EAC upon Average Wholesale Price (AWP) or AWP minus a specific percentage to reflect the prices pharmacists actually pay for the drug products.¹¹

At the same time that the Medicaid drug program intended to pay the actual, or estimated acquisition cost, incurred by the pharmacy for a specific drug product, Medicaid regulations also specified that pharmacies were to be paid a 'reasonable dispensing fee.' Medicaid program materials further describe a 'reasonable dispensing fee' as "an established dispensing fee to cover the pharmacy's overhead and profit."¹²

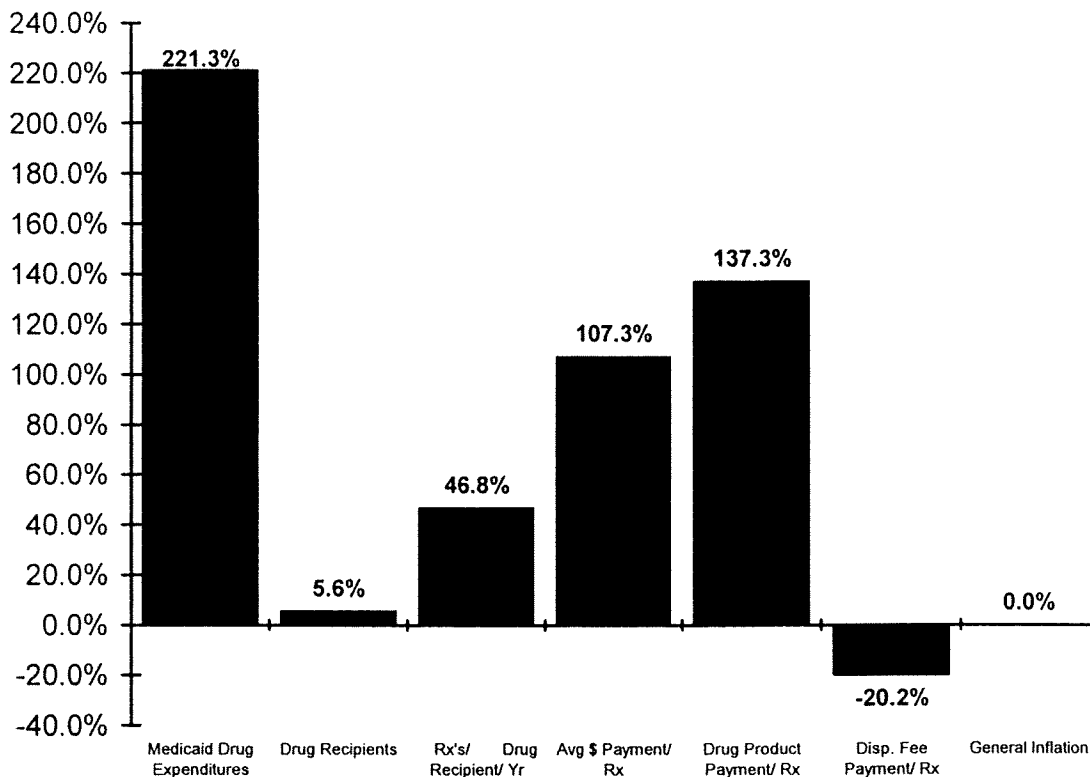
The Medicaid Drug Rebate Program was established by Congress with the passage of the Omnibus Reconciliation Act of 1990 and began operation January 1, 1991. After several legislative revisions to the program in the early 1990s, the rebate program has remained unchanged for nearly a decade. Drug firms must voluntarily agree to participate in this program in order to have their drug products covered by the Medicaid program. The rebate agreement obligates the drug firm to report to CMS its average manufacturer price (AMP) and its best price for each drug product (by NDC number) on a quarterly basis. State Medicaid programs, then, have to report to CMS and each participating drug firm the quantity of each drug product (by NDC) paid for by the state's Medicaid program in a given quarter. This unit volume is used to calculate the amount of rebate due based on the rebate formulae specified in statute. Simplistically, drug firms selling single source or innovator multiple source drug products (off-patent brands) must pay a rebate which is the greater of: (1) 15.1 percent of the AMP; (2) or the AMP less the best price offered to certain classes of trade. In addition, an inflation adjustment rebate factor is also due. Non-innovator multiple source drugs (off-patent generics or non-originator brands) pay a fixed percentage rebate of 11% of AMP. These generic drug products are not subject to either the best price calculation or the inflation adjustment rebate.

States' Medicaid programs may, at their discretion, develop state rebates in addition to the federally mandated rebates. Only a handful of states took advantage of the additional state rebate option prior to 2000 (most notably California), but many states have initiated or are exploring how to develop a state rebate above and beyond the federally mandated rebates. The Drug Rebate Program in 1992 provided payments of about \$1 billion dollars versus overall drug program costs of \$7.1 billion. By 2002 the Drug Rebate Program produced nearly \$6 billion in revenue that is shared by the states and the federal Medicaid program to offset the almost \$30 billion spent on total Medicaid drug expenditures. The rebate revenue is shared in proportion to the state and federal contributions to each state's Medicaid program costs. The rebate program produces revenue representing more than 20-percent of total Medicaid drug program expenditures. States would not easily make up the revenue produced by the Medicaid Drug Rebate program if the rebate program were to be reduced substantially or removed.

Sources of Growth in Medicaid Drug Expenditures

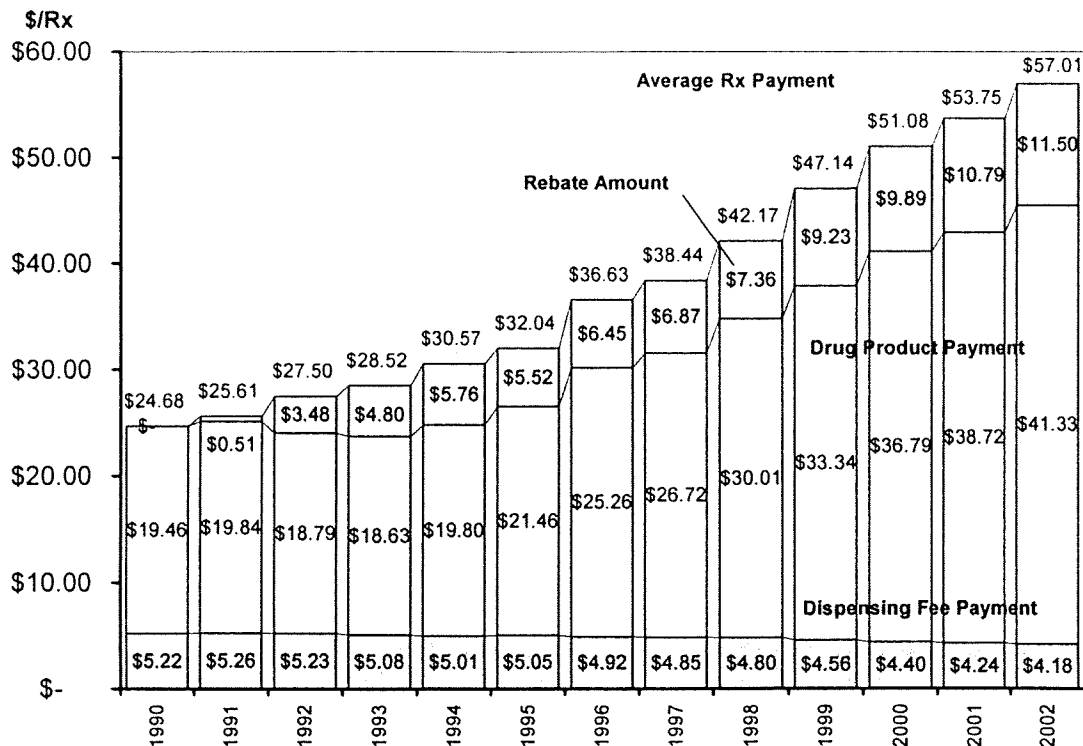
Between 1992 and 2002, Medicaid drug program expenditures (adjusted for constant dollars) increased 221 percent.¹³ This rapid growth is one driver of the interest in revisiting Medicaid payment policy and ensuring that it is optimally designed. In this same period, the number of drug recipients decreased about 6 percent, while the drug utilization rate (prescriptions per person per year) increased nearly 46.8 percent. The average payment per prescription grew more than 107 percent with the manufacturer's drug product cost accounting for a 137 percent increase while pharmacy dispensing fees actually decreased 20 percent, in constant dollars, over the last decade (see Exhibits 2 and 3).

Exhibit 2: U.S. Medicaid Drug Expenditures Percent Change in Major Components: 1992 to 2002 in Inflation Adjusted \$



SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in CMS/HCFR-2082 Reports (adjudicated & paid claims), CMS/HCFR-64 Reports (budgeted and expended funds), CMS/HCFR Medicaid Drug Utilization public use files, and the annual volumes of Pharmaceutical Benefits Under State Medical Assistance Programs (Reston, VA: National Pharmaceutical Council, 1990 to 2002).

There are two lessons here. First, drug product prices at the manufacturer level are the major source of increase in Medicaid drug program expenditures. Thus, it is important to focus on this component of the payment policy. Second, these data suggest that pharmacy dispensing fees have not been a source of growth in drug program expenditures and that reductions to pharmacy dispensing fees have not been an effective way to reduce prices at the manufacturer level. Medicaid programs do not purchase drug products directly from manufacturers, but rather prescriptions are purchased through local pharmacies. If management of growth in drug product costs is the desired outcome, the efforts to manage this cost must be focused primarily at the manufacturer level.

Exhibit 3: U.S. Medicaid Average Prescription Payment, Drug Product Payment, and Dispensing Fee: 1990 to 2002 (Constant 2002 \$)

SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in CMS/HCFR-2002 Reports (adjudicated & paid claims); CMS/HCFR-04 Reports (budgeted and expended funds); CMS/HCFR Medicaid Drug Utilization public use files; and the annual volumes of Pharmaceutical Benefits Under State Medical Assistance Programs (Reston, VA: National Pharmaceutical Council, 1990 to 2002).

Drug Prices and Pharmacy Payment

The payment amount for drug products to pharmacies and other providers under Medicaid and Medicare cannot be viewed in isolation from the other payments to such providers for storage, handling, counseling, dispensing, billing, record-keeping, and administration. In both the Medicaid and the Medicare program, drug payment policy incorporates two components: a component directly representing the cost of professional services and a component representing drug product costs. Note that, deliberately or not, the drug cost component of the payment has typically offered a margin relative to acquisition costs. This may be appropriate since certain other costs (such as drug inventory and storage, accounts receivable, uncollectible claims and copays, and the cost of capital) vary in proportion to the cost of the drug. In the Medicaid case, many other components of dispensing costs, such as pharmacist time, may be more appropriately viewed as varying according to the number of prescriptions dispensed rather than the cost of the drug product. For these components, a per-unit dispensing fee is appropriate. In addition, as pharmacists provide collaborative services with physicians and other health care providers that assure appropriate medication therapy management a service fee component may also be appropriate.

The drug cost component of the Medicaid and Medicare Part B drug payment systems has historically been based on the publicly available price known as the "Average Wholesale Price" (AWP). This price, however, has become controversial because it is only a suggested (or list) price, but not an actual transaction price. Medicaid programs typically reduce the payment to pharmacies for a drug product by an amount ranging from 5 to 15 percent (varies by state) off of AWP.¹⁴ Certain other drug products under Medicaid, i.e., non-innovator multiple source (NMS) drugs (i.e., generics) are paid

based on a Federal upper limit (FUL), also known as a maximum allowable cost (MAC) limit and some states have state MACs on many more drug products than included on the federal FUL list. This FUL or MAC is not directly based on AWP, but is almost always substantially less than AWP for most generic drug products.

Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians.¹⁵ This is particularly true for generic drugs. At the same time, these experts agree that Medicaid dispensing fees are low relative to actual dispensing costs. One panel member commented, "If it weren't for the AWP spread, the pharmacies would be out of business." Payments based on the cost structure experienced by pharmacies may warrant payment of a reasonable and managed spread (an amount paid above the actual acquisition cost), in addition to a fixed dispensing fee and an appropriate service fee for medication therapy management. Therefore, reform of the drug product cost component of the payment system must be considered in association with reform of other components of the payment system.

2.4 Medicare Part B Drug Program and Expenditures

Currently, Medicare Part B generally covers drugs that are "incident to" a physician's service, durable medical equipment (DME) drugs, and drugs specifically covered by statute (for example, oral immunosuppressive drugs). Drugs that fall under the category of "incident to a physician's service" include drugs that cannot be self-administered such as injectable and intravenous agents for oncology, rheumatoid arthritis, and nausea. Part B drug expenditures grew from \$3.3 billion in 1998 to \$8.4 billion in 2002 nearly a three-fold increase in four years. Both payment method and trends for specific drugs within the Medicare Part B drug program have contributed to the growth in drug program expenditures.

Legislative and Regulatory History

From 1991 to 1998, the method of payment for drugs under Medicare Part B was based on the lower of: (1) estimated acquisition cost (EAC) or (2) average wholesale price (AWP) for a drug. If a drug was available from multiple sources, the payment was based on the median of the national average wholesale prices for generic equivalents. The estimated acquisition costs were defined as the "actual invoice prices paid by the providers furnishing the drug" and were to be determined based on provider surveys.¹⁶ In addition to the drug cost, the survey was to include indirect costs such as inventory, waste, and spoilage. Practically, the fiscal intermediaries set the payment limit as AWP according to the Red Book or First Databank's Blue Book. In contrast, in the early 1990s the Medicaid program was using EAC defined by most states as AWP -X percent, with the reduction to AWP ranging from 5 to 15 percent. The statutory basis for Medicare drug payments changed to AWP - 5 percent beginning on January 1, 1998. Another change known as 'least costly alternative' (LCA) developed through certain fiscal intermediaries as early as mid-1997. The LCA approach reasoned that when there were two or more similar or equivalent therapeutic alternatives, the Medicare Part B payment could be limited to the cost of the least costly alternative. This LCA approach started in just a few states, but by 2002 had spread to more than 40 states.

Beginning January 1, 2004, the payment amount for drugs administered by physicians was revised based on statutory language contained in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA; Pub.L. 108-173). The new payment method was to be 85 percent of the AWP as of April 1, 2004 for most physician-administered drugs with certain exceptions. The MMA further described payment rules to be implemented January 1, 2005 based on manufacturer submission of data on a drug's average sale price (ASP). The ASP is defined in the MMA as the amount of the manufacturer's sales revenue to all purchasers divided by the total number of units sold in a given quarter. The manufacturer should include the effect of "volume discounts, prompt pay

discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program)."¹⁷

At the same time that the MMA altered its payment policy for the drugs covered by Part B, it also specified new procedures for calculating the practice expense relative value units (RVUs) associated with drug administration services for certain physician specialties and for clinical oncology nurses.¹⁸

Sources of Growth in Medicare Part B Expenditures

As in the Medicaid case, there has also been rapid growth in Medicare Part B drug expenditures. Analysis of the sources of this growth reveals that only a few of the approximately 450 covered drugs account for most of the spending. As noted earlier, drug expenditures in 1998 were about \$3.3 billion and this amount grew to more than \$8.4 billion by 2002.¹⁹ During the same period (1998 to 2002), the Medicare enrollment grew only 1.4 percent per year while the drug spending grew an average of 27 percent per year. The vast majority (77 percent) of the Medicare Part B drug expense is paid to oncologists and urologists. Oncologist-based drug expenditures grew from \$1.2 billion in 1998 to \$3.8 billion in 2002 with the spending growth from 2001 to 2002 at 41 percent. The spending on drugs under Medicare Part B is highly concentrated with 7 of the approximately 450 drugs accounting for 49 percent of the spending (\$4.0 billion out of \$8.4 billion). Nineteen drugs accounted for 75 percent of the total drug spend and 33 drugs accounted for 86 percent of the total. Both drug product price increases at the manufacturer level and increases in utilization appear to have been the major contributors to growth in drug expenditures for the Medicare Part B program.

Drug Payment and Provider Expenses

Panel members agreed that, under the 1998-2003 payment methodology, the administration of prescription drugs covered by Part B generated high profit margins for oncologists, urologists, and other physicians. In addition, they commented that the financial incentives created by this profitability played a large and problematic role in prescribing decisions, i.e., prescribers responded to these high margins by tending towards administering more (and more expensive drugs) than might be medically necessary or optimal for the health of the patient.

If physicians' profits are a function of quantities administered and the spread between the AWP and the transaction price, manufacturers' profits are a function of quantities administered and transaction prices. Thus, manufacturers' rational response in this setting is to set transaction prices high (to increase their profits directly) and AWP's even higher (to increase physician profits and thereby the demand for their drug). Particularly in the Medicare setting, where the payment accrues to the prescriber, the ideal is for the third party payment system to create neutral incentives regarding the amount and nature of drugs administered.²⁰ A payment system based on actual acquisition costs accomplishes this goal. Note that the ASP-based payment policy, which Medicare Part B will use beginning in 2005, is such a system.

Now that drug payments are being revised downwards, the affected physicians are raising concerns about the level of payments to physicians and nurses for drug administration.²¹ The oncologists' position is an acknowledgement that drug cost payments should be reduced, but at the same time the fee for drug administration needs to be evaluated and increased.

explain why a chain pharmacy pays a higher price, even though it purchases a substantially larger volume of a drug product than an individual physician typically purchases. The structural barriers of monopoly position and statutory prohibitions on price arbitrage mean that the purchasers who get the lowest price in the market are not necessarily the most efficient purchasers in the market. Because class-of-trade differentials exist and are outside of the control of the purchaser, an accurate approach to estimating actual acquisition costs must take into account the class of trade pricing practices of drug firms. The practice of class of trade pricing is not usually disclosed directly by drug manufacturers and could experience change as the dynamics of the pharmaceutical marketplace evolve during the implementation and operation of the new Medicare outpatient drug benefit.

Drug Product Type Variations

The pricing patterns of brand name drug products and generic drug products can be quite different. For most brand name drug products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is reasonably predictable. That is, the WAC is equal to, or very close to (+ or - 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP is typically 20 to 25 percent above the WAC or, alternatively, WAC is 16.67 or 20 percent below AWP. In such cases, a payment policy based on AWP (i.e., usually AWP minus a certain percent) may be relatively accurate. This pricing pattern holds for community pharmacy classes of trade (independents, chains, and food & drug stores), but not necessarily for other classes of trade (i.e., mail order pharmacies, HMOs and health plan pharmacies, long term care, physicians or clinics, hospitals, or state and federal facilities or programs). Some of these other classes of trade control the demand (i.e., prescribe or influence the drug prescribed) and are reimbursed by a third party based on a percent off of AWP or a percent above WAC. When these other providers can actually purchase the drug product from the manufacturer, and when the manufacturer deliberately creates a large and hidden spread between actual acquisition cost and the reimbursement amount, then the physician or other provider has a very strong financial incentive to prescribe their drug. This non-transparent spread leads to a financial incentive to prescribe more often and to prescribe higher-priced drugs over lower-priced drugs even when they are not necessarily the most cost-effective alternative. These financial incentives from the hidden spreads may be one factor contributing to the rapid growth of Medicare Part B drug program expenditures over the past four years.

Once a brand name drug product loses its patent and market exclusivity, the brand name drug may face price competition from generic versions of the drug product. Usually the brand manufacturer does not compete on price with generics for the community pharmacy class of trade. This means that the AWP and WAC relationship to actual acquisition cost discussed earlier for brand name drugs still holds. However, brand manufacturers sometimes offer substantial discounts relative to WAC to certain classes of trade (i.e., hospitals, long term care, health plans, and physicians). This may keep the actual acquisition cost of the brand drug somewhat price competitive in non-community pharmacy settings, and particularly when the provider receives payments keyed to list prices may result in excessive financial incentives to prescribe or use the brand name rather than a generic equivalent.

Price competition begins when the market is entered by the first generic drug product that is a therapeutically equivalent version of a brand name drug product made by the drug firm that holds the original NDA for a given chemical entity. When two or more generic drug products enter the marketplace they typically compete on price with each other even though the brand name product usually does not compete on price. The first generic will typically enter the market at a list price (both AWP and WAC, if a WAC is reported) that is 10 to 30 percent below the originator brand price. Often the price competition among generic versions of a drug product will be reflected by one or two decreases in list prices (AWP and WAC) in the first six to twelve months after generic entry, but after that time it is rare to see generic list prices change and at some point in time the generic list prices for some drugs may even begin to rise again.

The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWP's that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition cost for generics. Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts in lower AWP or WAC list prices. Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs. Medicaid drug payment policy reflects the lower market prices for generic drugs by placing a FUL (a federal MAC or a state MAC) on many generic products.

Geographic Variations

Geographical variations in the actual drug cost at the manufacturer level are not common. Once one has accounted for class of trade differentials, most drugs have the same list prices (AWP and WAC) regardless of where they are purchased or used. In the few cases where a specific drug may have prices that vary by region, the variation is often in response to certain third party payment methods (i.e., the Least Costly Alternative (LCA) method) of paying for therapeutic alternates under Medicare Part B by certain fiscal intermediaries.

In contrast to the general uniformity of prescription drug prices, the cost of professional services (i.e., physician fees or pharmacy fees) usually varies by geographic region. Both physician and pharmacy costs of providing the required services that accompany prescription drugs vary by geographic region due to differences in rent, salaries, general cost of living, insurance, and other factors. To the extent that the drug cost component of the payment policy is intended to also cover part, or all, of other costs associated with drug provision (e.g., storage and handling, or counseling and medication therapy management), there may be a need for this component to vary by region. Also, for the reasons above, changes in drug product payment policy may have different impacts upon providers and pharmacies across regions. These same factors may also vary across geographic locations (rural versus urban) within the same region.

5.0 Options for Estimating Acquisition Costs

5.1 Evaluation Criteria

The previous sections described essential background issues for the estimation of actual acquisition costs. This section lays out criteria for evaluating potential estimation methods and discusses the data that are available and potentially available for this purpose. Several options are then described and evaluated for their strengths and weaknesses with respect to these criteria. The criteria presented below emerged from the authors' analysis and from the Expert Panel's discussion. Because the estimation method would ultimately be used in the context of drug payment, some of the criteria bear on payment policy as well as on estimation approaches *per se*. Similar criteria have previously been applied to evaluation of alternative payment methods for multi-source prescription drugs.³⁰

Accurate and Reliable

The Medicaid and Medicare programs should have access to accurate and reliable information regarding the actual acquisition costs for prescription drugs for each channel of distribution. Based on such accurate and reliable cost data, these programs may decide that the payment rate to pharmacies or physicians should include a percent markup on brand name drug product costs, and an

even greater markup for generic drugs, but this practice should be an explicit decision of the policy maker and not an implicit and hidden factor left in the control of the pharmaceutical manufacturer. In this context, 'accuracy' concerns the degree to which the price used in payment policy is close to, or the same as, the amount actually paid by a pharmacy or physician for a given drug product. 'Reliability' is the degree to which the price used in payment is consistent for similar prescription claims.

Based on Markets: Estimated acquisition costs are more likely to be accurate if they are based on actual transaction prices in the market (i.e., the average selling price). Market or actual prices can be contrasted both to list prices, set by manufacturers, and to administered prices, set by the government. This approach, however, requires transparency of transaction prices.

Generally and Widely Available

Any price list used by the Medicaid or Medicare program should reflect 'generally and widely available prices,' that is, any provider paid according to the payment policy should be able to procure drugs at the published payment amount.

Estimated Separately by Class of Trade: Because actual acquisition costs vary by class of trade, the estimation methodology must take into account these differentials in order to generate drug product payments that are both accurate and reflect generally and widely available prices. For example, when a drug manufacturer sets lower prices for one class of trade (e.g., physicians) versus another class of trade (e.g., community pharmacies), the result is that the average of the prices across these two classes of trade will overpay the class with the lower price (physicians) and will under pay the class with the higher price (pharmacies). In addition to class of trade differences, drug product prices may differ for other reasons such as geographic or regional (urban versus rural) variations. A payment policy that does not account for different acquisition costs by class of trade, or other factors, may preclude certain providers from the market for reasons beyond their control. For providers within the same class of trade, the concept of 'generally and widely available prices' is appropriate and helpful to assure that a wide spectrum of physicians or pharmacies will be willing to participate in the program.

Current and Up-to-Date

An effective price list must be based on current prices that are updated regularly. Drug prices are set by drug manufacturers and can change whenever the manufacturer decides to adjust the price (usually an increase). Most manufacturers change drug product prices every 6 to 12 months with the average interval being about 10 to 11 months, however, some drug products may change their prices much more frequently. Claritin, for example, in the last three years before being switched to over-the-counter status raised its price every three months and had a cumulative annual price increase in 2002 of 21.2 percent. If provider payments for prescription drugs were being revised only once a year, a pharmacy would be losing as much as 20 percent on each Claritin prescription dispensed near the end of the year.

An effective payment policy should not set drug product payment amounts that consistently result in an underpayment due to delayed updates of prices. The drug product payment database needs to be electronically available using the standard electronic data interchange protocols in the prescription marketplace, and it needs to be updated on a virtual basis with a minimum of time delay (1 week or less) in updating price changes.

Transparent and Accessible

The price list and payment policy must be readily available to, and clearly understood by, market participants. Those covered by the payment policy should understand the source of data and how those data are translated into the payment policy. In addition, any price list to be used in payment for prescription drug products must be in an easily accessible and usable format. This format must be compatible with pharmacy and claims processor computer and software systems. Obviously, an electronic database is essential for both efficient publication and use. Pharmacy and physician providers must be able to easily confirm current payment at the time of prescribing, or dispensing, a prescription.

Adequate Compensation to Providers and Pharmacies

While the drug product component of the payment policy should be based on actual acquisition costs, the payment policy as a whole should adequately compensate providers for the storage, handling, dispensing, and administration of prescription drugs and for their professional services. This is essential to ensure that beneficiaries have access to quality care, without triggering perverse incentives. At present, the margins, or spreads, between drug product payment amount and actual acquisition cost may compensate providers (physicians and pharmacies) for deficiencies elsewhere in the payment system. If and when the method for estimating acquisition costs is altered, it may be desirable to reconsider the payment policy as a whole.

Incentives for Pharmacies and Providers to Supply Drugs

Any payment scheme creates financial incentives for providers. Ideally, these incentives foster quality and cost-effectiveness. Two main dimensions of provider incentives have already been discussed. First, adequate compensation gives providers incentives to participate in the program and supports beneficiary access. Second, payment based on actual acquisition costs creates neutral incentives for providers regarding the choice of drug therapy with the result that providers are more likely to focus on the choice of therapy that is optimal for the patient and economically efficient for the program.

Incentives for Key Parties to Provide Data

Pricing data will be needed from various levels in the market to determine appropriate payment amounts. If the program establishes fair, but not excessive prices, providers will be more likely to participate in good faith than if the program tries to implement below-market prices that overly squeeze the provider's margins. In addition, terms must be clearly defined so that firms understand what data they are expected to submit and so that analysts understand what data they have received.

Authority to conduct audits of drug manufacturers and of all provider types may provide some incentive for firms to participate in reasonable requests for data. Other incentives need to be identified and examined. If manufacturer data submission is chosen as a viable alternative, the drug firm can be asked to certify the data provided in a manner similar to that specified in the corporate integrity agreements (CIAs) developed by the Department of Justice for use by those drug firms that have settled fraud allegations related to Medicaid and Medicare drug pricing.

The consequences of inaccurately or incompletely defined pricing terms and concepts can be seen in the case of certain drug manufacturers who may have underpaid the Medicaid drug rebate program through various methods that are questionable and possibly illegal. For example, a drug firm may charge a managed care pharmacy the regular price for a drug product for one-half of the year and then charge less than 10 percent of the regular price (i.e., a 'nominal' price) for the other half of the year. In this way the drug firm has effectively given the managed care pharmacy a 45 percent discount, but

this discount, arguably, does not have to be reported as a 'best price' discount. The sale of drug product at less than 10 percent of the regular price is considered a 'nominal price' (intended to benefit free clinics and groups like Planned Parenthood) and is exempt from the best price calculation. In this case the definition of a 'nominal price' has been gamed to allow passing on an effective discount arguably without having to declare the discount as a best price for purposes of calculating the Medicaid best price rebate.

Other Considerations

In addition to meeting the criteria above, any payment policy must be politically acceptable and feasible to implement. Payment policy may need to vary to account for acquisition cost differences across: (1) provider types (i.e., classes of trade), (2) program types (i.e., Medicaid, Medicare Part B, and Medicare Part D), (3) drug product types (i.e., single source brands, innovator multiple source brands, and generics), and (4) geographic locations. For example, policies may seek to acknowledge the greater volatility of generic prices or promote competition among therapeutic alternates, as the least costly alternative (LCA) policy does. Finally, a regional adjustment to the payment for storage, handling and dispensing of a drug product may be necessary to address regional variations in rent, labor, and distribution costs.

5.2 Sources for Drug Price Data

A method for estimating acquisition costs must be based on data. In theory, one could capture data on all market transactions and use it to estimate the prices being paid for each and every drug product at each and every point in the market. However, this is not possible given the complexity and volume of market transactions. There are four basic sources of accessible data: (1) primary data from supply chain transactions; (2) secondary data on list prices from drug price and clinical information data firms; (3) secondary data on invoice prices from drug market and utilization data firms; and (4) legislative and regulatory price databases. The basic sources of primary and secondary data are briefly outlined and then discussed below.

Primary Data from Supply Chain Transactions

There are five potential sources of electronic transaction data from the supply side: (1) manufacturer sales transactions to direct purchasers (mostly wholesalers and large chains); (2) wholesaler sales to pharmacies and other purchasers; (3) pharmacy purchase invoices from wholesalers and manufacturers; (4) pharmacy sales transaction data submitted to payers; and (5) third-party payment transactions for prescriptions provided by pharmacies or other providers (i.e., physicians). Only the first three of these transactions are actual purchase prices at the manufacturer or wholesaler level that could be used to establish appropriate payments to pharmacies or physicians. In fact, these electronic transaction data sources are used by various drug price database firms (i.e., IMS Health, Verispan, First Data Bank, MediSpan, and Red Book) to collect and aggregate drug pricing and utilization data.

Secondary Data on List Prices

Three commercially available drug price databases track list prices of drug products in the U.S. market at the AWP and WAC levels. These databases are: (1) the Blue Book (First DataBank, Hearst Publishing Co., Palo Alto, CA); (2) MediSpan Master Drug DataBase and PriceChek PC (Facts & Comparisons, Wolters Kluwer Health, Inc., Indianapolis, IN); and (3) the Red Book (Thomson-Medical Economics, Montvale, NJ). Historically, each of these firms published a price list in printed format once a year with quarterly updates. Since the mid-1980s, however, the electronic version of these databases has been the primary format for price list publication. These databases are updated on a continuous (daily) basis. In addition to price data, these databases also contain or link to

other databases that provide descriptive and clinical information on drug products including therapeutic class and uses, drug interactions, patent and regulatory status, therapeutic equivalence and generic alternatives, and many other useful data elements.

The principal users of these drug price databases are pharmacies and third party programs. Pharmacies use the drug price and clinical information database on their in-store computers for pricing, filling prescriptions, drug interaction screening, and submission of third party prescription claims. Third party payers (public and private) use these databases to screen, adjudicate, and determine payment for covered prescriptions. Virtually every third party program (public or private), or its claims processor, use one of these drug price databases as the source for AWP, or WAC, values that serve as the basis for calculating the price that a pharmacy will be paid for each drug product based on the NDC number. This price information is then used according to the contractual pricing formula to pay the pharmacy for the prescriptions dispensed to eligible recipients. The vast majority (more than 40) of the state Medicaid programs use First DataBank's drug price information as the basis for prescription drug payments to pharmacists and other providers.³¹

Secondary Data on Invoice Prices

Several commercial drug market and utilization databases are available with fairly comprehensive data on revenue, units sold, and price per unit for each prescription drug product on the market. These databases are: (1) National Sales Perspectives (NSP) and National Prescription Audit (NPA) (IMS Health, Plymouth Meeting, PA); (2) Source Prescription Audit (SPA) (Scott Levin, a Division of Verispan); and (3) NDC Prescription Price Analyzer and NDC Prescription Price Reporter (NDC Health, Inc). Each of these databases was developed primarily as a source of market intelligence information for drug manufacturers to track how their drug products are performing in the market compared with other similar drug products. Since these databases are based on transaction invoice data from the market there is a brief lag time from actual transaction to availability of data. For certain database products the lag time may be as short as one or two weeks, but for most market databases there is a lag of six to eight weeks.

The IMS NSP database is transaction data from wholesaler and manufacturer sales invoices into pharmacies and other purchasers. The IMS NPA database is based on retail pharmacy sales of prescriptions to patients by various methods of payment including cash, private third party, and Medicaid. The Scott Levin SPA database and the NDC Health databases are similar to the IMS NPA database in that they obtain their data from retail pharmacy sales of prescriptions to patients by various methods of payment including cash, private third party, and Medicaid. Each of these retail sales databases captures their data from pharmacy transactions on computer systems in each pharmacy. All sources claim to obtain data from 35,000 to 45,000 out of the total 53,000 community pharmacies in the United States.

The principal users of these drug market and utilization databases are pharmaceutical manufacturers who want to track how their drug product is selling compared to other similar drugs. Purchasing reports from these databases can be quite expensive—tens of thousands of dollars to millions of dollars. Manufacturers use these databases to track market shares, sales volume, new and total prescriptions, generic substitution, therapeutic switching, amount and effect of promotional activities, impact of formulary preferences and restrictions, impact of copays and co-insurance, compliance and persistence of drug therapy, and other issues.

Legislative and Regulatory Drug Price Databases

There are several databases with price information that have been created for statutory or regulatory purposes related to various government programs. These government databases include: (1) the Medicaid drug rebate database; (2) the Medicaid drug utilization database; (3) the Texas Vendor Drug

Program manufacturer price database; (4) the federal supply schedule for prescription drugs; (5) the VA price database; (6) the 340B program price schedule for prescription drugs; (7) the federal ceiling price for prescription drugs; (8) the TriServices Support Center price schedule for prescription drugs; and (9) the Medicare Part B average selling price (ASP) database authorized under the newly passed MMA.

The first three of these databases collect data on manufacturer's prices to community pharmacies (items 1 and 3) or from community pharmacies to Medicaid recipients (item 2). As such these databases hold potential for use in setting or evaluating payment amounts for prescription drug products provided to Medicaid and Medicare Part B recipients. The prices reported in the other government databases (e.g., VA, FSS, or 340B prices) are prices that are not generally and widely available to community pharmacies or physicians and, therefore, these price databases hold little utility in setting payment rates for prescription drugs in the private market. Description of these government programs and how their prices are determined has been described elsewhere.³²

CMS provides national administrative services that support the operation of the Medicaid drug rebate program created by the Omnibus Reconciliation Act of 1990 (OBRA 90). A manufacturer must voluntarily participate in the Medicaid drug rebate program in order for their drug products to be covered in the Medicaid program. To facilitate the implementation of the Medicaid drug rebate program, CMS (formerly HCFA) collects pricing data from all participating drug manufacturers for all drug products sold by that manufacturer including the average manufacturer price (AMP) and the 'best price' to any non-exempt purchaser. This information, however, by statute is considered proprietary and confidential and cannot be publicly released by CMS.

5.3 Description and Evaluation of Options

This section describes and evaluates options for estimating acquisition costs for drugs covered under Medicaid and Medicare Part B programs. These options are categorized according to the primary source of the data.

Option 1. Primary Data from Manufacturers

One broad option for estimating acquisition costs is to collect data on average selling prices from manufacturers or to work with existing sources of such data, such as data used for the Medicaid drug rebate program, the Texas Vendor Drug Program, or the Medicare Part B program (ASP). Average selling prices, with adjustment for a wholesaler margin, provides a reasonable estimate of acquisition costs, if collected and reported by class of trade.

There are barriers to using the existing Medicaid database for pricing in the Medicaid and Medicare Part B programs. First, the OBRA 90 Act that created the drug rebate program includes provisions, at the manufacturers' insistence, which specify that the AMP and best price data are to be treated as proprietary and confidential. While this data might be very useful in creating a price list, to date it has not been released or used for purposes other than operation of the drug rebate program.

A feasible alternative is to work with the data from the Texas Drug Vendor (VDP) program. Based on statutory authority at the state level, the Texas VDP requires submission of pricing data by the manufacturer of every drug product desiring to be covered by Texas Medicaid. While there are certain concerns regarding how prices and classes of trade are defined, these data have already been collected and are potentially available for research. For the Texas VDP, manufacturers are responsible for providing the data on each drug product to be covered and for updating those prices in a timely manner as they change periodically. The data are entered into a database based on each drug

product's unique NDC number. The resulting data base is updated when notice of price changes arrive or within a few days of that time.

A third alternative is original data collection, following the Texas approach, but using enhanced processes and definitions. While this alternative may represent the ideal, it also requires significant effort and may require new legislation or regulations in other states or at the federal level.

Advantages and Disadvantages. Data from manufacturers could be used to price the entire list of drugs covered by both Medicaid and Medicare Part B and can be applied to both brand and generic drugs. Different prices for various classes of trade could be accommodated (e.g., community pharmacies, long term care, physicians, hospitals, and others). The database could be updated on a virtual basis, which essentially means changes on any given business day with a processing time lag of less than one week. In addition, transaction data from manufacturers has the potential to incorporate all forms of discounts, rebates, and other forms of economic incentives.

The disadvantages of this approach are that it does not technically generate providers' acquisition costs, but manufacturers' net revenue and wholesaler cost. An adjustment to account for wholesaler markup (operating margin) is required to convert this price into a pharmacy or physician acquisition cost. In addition, this approach may require new regulation or legislation in order to enable CMS to gather this data from manufacturers (beyond what is being gathered for AMP under Medicaid or ASP under Medicare) as they are unlikely to submit it voluntarily. However, national implementation of manufacturer data collection is far more cost-efficient for both the government and for drug firms than having each state set up its own system, as Texas has. If a national data collection is used, there should be coordination between efforts related to Medicaid and Medicare.

Option 2. Careful Analysis of List Prices

A second option to be explored is tracking the AWP:WAC ratio over time in one of the existing drug price databases (e.g., First DataBank or MediSpan). Medicaid and most other third parties currently pay based on AWP or a function of AWP. This means that if the AWP increases, even if the WAC or the actual price to the pharmacy or provider does not increase, the payment to the pharmacy or the provider will increase. Most drug products have had a constant AWP:WAC ratio over time and as long as the ratio stays constant, then $AWP - X$ percent or $WAC + X$ percent will function similarly in terms of effect on total payment for a drug product. If however, the AWP:WAC ratio changes (i.e., the gap gets wider), the third party payer using AWP minus as the basis for drug product payments will then be paying a larger markup on the drug product cost than a third party payer basing payments on WAC plus.

There is evidence to suggest that a number of major drug manufacturers increased the AWP:WAC ratio for the vast majority (90 percent or more) of their drug products between October 2001 and July 2002.³³ The shift resulted in most drug products of these firms moving their AWP from 20 percent to 25 percent above the WAC. This move means that for drug products reimbursed by Medicaid or private third party programs based on a percent off of AWP, these programs paid 5 percent more for each prescription. This change was initiated and driven by drug manufacturers, even though most of the benefit may accrue to the pharmacy. This is an example of the type of 'gaming' that a payment system should be routinely monitoring. Under this option an assessment will be made of the economic impact of the AWP:WAC change that occurred in late 2001 and early 2002. A possible change in the payment method to a $WAC + X$ percent may be warranted and would help to avoid this particular form of 'gaming.'

Another gaming issue can be addressed using the existing drug price databases. This issue is concerned with relabeling of single source drug products (patent protected brands) under a relabeler's new NDC number and setting a new and higher AWP. Most third party payers have pricing formulas

and methods that assume that there is only one AWP price for a single source drug. Actually, nearly all of the most prescribed single source brand name drug products have several relabelers who have established their own NDC numbers and have set their own AWP for the originator brand product. Often these relabeler NDCs are not sold to, or available to all purchasers, but they are sold only to a special class of trade such as physician dispensers, mail order pharmacies, or long term care facilities. The originator brand may have a price of \$2 per tablet while the relabeler may have set the new AWP at \$3 per tablet. Using the payment method of most third party programs including most Medicaid programs, the higher price will be paid and the program won't even know that it was an inflated AWP. This phenomenon is not a small matter, the number of relabeler NDCs in the MediSpan drug price database grew from 791 in 1990 to more than 20,000 in 2002.³⁴

The existing drug price databases can also be used to efficiently identify drugs that should have a federal upper limit (FUL) or MAC established and to calculate that MAC. The method for establishing and updating the FUL amount could be reviewed and alternative formulae for calculating the FUL can be examined according to established criteria.³⁵

Advantages and Disadvantages. This approach could be used for the entire list of drugs of both Medicaid and Medicare Part B and can be tailored to special problems with both brand name single source drugs and generic off-patent drugs. Specific prices to certain structural classes of trade (e.g., long term care, physicians, hospitals, and mail order) could be isolated and filtered out or taken into account. With list price data, it is not possible to analyze class of trade differences directly; one must determine whether certain relabelers sell only to specific classes of trade and not to others. The database and pricing amounts could be updated on a virtual basis which essentially means changes on any given business day with less than one week processing time lag. The disadvantage of this approach is that both the AWP and the WAC are list prices and not actual transaction prices. Also, the standard drug databases have only one AWP and one WAC for all buyers, despite the fact that certain classes of trade may routinely receive substantial discounts off of AWP or WAC. Even though the methods described in this section may move the payment closer to the actual price, there is no direct link to actual prices.

Option 3. IMS Invoice Data

The third option is to use a drug marketing and utilization database, IMS' National Sales Perspectives (NSP - formerly Retail and Provider Perspectives, RPP). This database comes from wholesaler and manufacturer invoices of pharmacy and other provider purchasers. Consequently, the data is broken down by class of trade for each drug product at the NDC level. The price most often used by wholesalers on their invoices is the WAC. IMS does take into account discounts shown on the line item of an invoice, but this type of discount is rarely given to community pharmacies. When price database WACs are compared with the IMS invoice cost per unit, the two are essentially the same. The strength, however, for the IMS NSP data set is that the invoice prices for certain classes of trade do show at least part of the discounts given to these other classes of trade such as clinics (and physicians), long term care facilities, in-house HMOs, hospitals, home health care, mail order pharmacies, and other government programs.

In particular, this approach may be a good way to estimate acquisition costs for Medicare Part B drugs provided by clinics and physician offices or by hospital outpatient facilities. While this database still will not capture all discounts, the adjusted invoice price is likely to be closer to the actual price than either AWP or WAC from the standard drug price databases. Other potential uses of the IMS databases in pricing can be explored and evaluated.

Advantages and Disadvantages. This approach will provide price estimates for Medicare Part B drugs that are closer to actual cost for clinics (and physicians) than either the standard WAC or AWP. The IMS NSP database has monthly updates with a 6 to 8 week delay in reporting. If CMS had

access to this data, little additional data processing would be necessary and the actual analysis would be fairly straightforward.

The disadvantage of this approach is that even the net invoice price reported does not take into account rebates or all forms of discounts or other forms of economic consideration. Also, the IMS database does not maintain its list of drug products with the NDC number attached to each drug product record. A database bridge will need to be created from IMS data to a drug price database such as MediSpan's Master Drug Data Base. In addition, IMS data is typically quite expensive, and IMS may be reluctant to allow its data to be used to set payment policy. IMS may be concerned either that such use would alienate its data suppliers (i.e., wholesalers, pharmacies, and other providers) and thus compromise its data products or that such use would cause its suppliers to manipulate their data to game the price list and thus compromise its product. Also, IMS may be concerned that use of this data for payment policy may alienate the major purchasers of their data (i.e., drug manufacturers).

Option 4. Wholesaler Survey

The fourth option is to survey wholesalers to determine either the wholesaler's actual cost from the manufacturer and/or the pharmacy's (or other provider's) actual cost from the wholesaler. Wholesaler data is the basis for secondary commercial data sources such as IMS Health. Also, the wholesalers would be able to break down sales into class of trade to identify price differences that are based on the structural factors in the pharmaceutical market. Data at pharmaceutical wholesalers is highly automated and electronic data interchange standards would make this process fairly efficient. As noted above, only three wholesalers account for greater than 85 percent of wholesale activity and about one-half of total manufacturer sales of prescription drug products. Wholesaler surveys could capture not only list and invoice prices from manufacturer to wholesaler and from wholesaler to pharmacy or provider, but also data on various discounts, certain types of rebates, chargebacks, and payment terms (e.g., delayed billing). Nearly all drug products in the prescription market would be in wholesaler databases, except for drugs that are mostly or exclusively sold direct from manufacturer to the provider or pharmacy.

In order to create a price list from a wholesaler survey, the contractor or entity organizing the data will have to acquire and match the data to a drug database (i.e., First DataBank or MediSpan) to obtain other drug product identifiers and information for describing and grouping drug products. A database bridge will need to be created from wholesaler data to a drug price database such as MediSpan's Master Drug Data Base.

Advantages and Disadvantages. This approach will provide price estimates for nearly all drugs in the market, although the data on branded drugs would be stronger than the data on generic drugs. In addition to AWP and WAC, the types and levels of discounts and other forms of economic consideration can be captured. Also, a wholesaler survey would enable estimation of the average selling price by class of trade. Wholesale data could be updated on a daily or weekly basis with little delay. Wholesaler survey data could be organized to serve as the basis for payment, but that would require public disclosure of the data used as the basis for payment. An alternative use of the wholesaler survey data would be as a validity check against other price data sources.

The disadvantages of this approach are that the wholesalers may be reluctant to co-operate because of the desire to maintain the confidentiality of their business practices. Wholesalers' data will miss certain rebates. Also, in certain key markets, such as the market for injectible drugs, many transactions go around the wholesaler.

In addition, a new wholesaler survey may be burdensome and redundant given that much of the information from wholesalers has already been collected and organized by the commercial database at

IMS Health, and the IMS database has the additional advantage of supplemental data from manufacturers and pharmacies.

Option 5. Provider Survey

The fifth option is to survey providers (primarily pharmacies and physicians) to determine amounts actually paid for specific drugs. On invoice prices and discounts or allowances could be identified by this approach. The sheer numbers of providers (100,000 or more administering drugs in office) and pharmacies (55,000) here are quite large; however, scientific sampling would be possible. Separate surveys would be needed for each class of trade, such as independent pharmacies, chain pharmacies, clinics (and physicians), long term care facilities, in-house HMOs, hospitals, home health care, mail order pharmacies, and other government programs. Moreover, surveys would need to be administered frequently (at least quarterly) in order to capture price changes.

This option would impose significant burden on providers given the sizes of the samples necessary and the number of individual drug products. Providers and pharmacies are less likely than wholesalers to have purchase and invoice data in an electronic form. Also, the compatibility of electronic formats is likely to be low due to the large numbers of competing pharmacy and practice management software products. Data would need to be converted to a common format, and a database bridge would need to connect the survey data to a major drug price database such as MediSpan's Master Drug Data Base.

Advantages and Disadvantages. This approach would provide price estimates for Medicare Part B drugs that would be closer to actual cost for clinics (and physicians) than either the standard WAC or AWP. It would have the potential to capture all rebates and discounts, though with a significant delay. However, it is not feasible to use provider surveys as the primary source of price data because of the burden of data collection. The potential value of this approach lies in generating confirmation of actual market prices for a very select set of drugs such as top drugs under Medicare Part B. In addition, these data could be used to spot check for price gaming behavior by manufacturers or providers.

The strengths and weaknesses of these data sources are summarized below:

Exhibit 6:

Summary of Strengths and Weaknesses of Data Sources for Estimation of Acquisition Costs

Manufacturer data	<p><i>Strengths:</i> Actual price, includes all discounts and rebates, available by class of trade, reasonable effort</p> <p><i>Weaknesses:</i> May need legislation or regulation, not technically an acquisition cost</p> <p>Conclusion: Strongest base data</p>
<p>List prices (e.g., AWP & WAC from MediSpan or First DataBank)</p>	<p><i>Strengths:</i> Widely used standard, minimum effort</p> <p><i>Weaknesses:</i> List prices (AWP and WAC) not actual prices, not class of trade specific</p> <p>Conclusion: Essential point of comparison</p>

Exhibit 6:**Summary of Strengths and Weaknesses of Data Sources
for Estimation of Acquisition Costs**

IMS invoice data	<i>Strengths:</i> Existing source of discounted invoice prices (list less invoice discounts), available by class of trade <i>Weaknesses:</i> Misses certain discounts and rebates, must be publicly available to serve as basis of payment Conclusion: Very helpful point of comparison
Wholesaler survey	<i>Strengths:</i> Potential source of invoice data, available by class of trade, moderate effort <i>Weaknesses:</i> Does not capture direct sales to chains or physicians, duplicative of IMS Conclusion: Helpful point of comparison, especially if IMS data not available
Provider survey	<i>Strengths:</i> Potential source of actual acquisition costs, can spot check for price gaming <i>Weaknesses:</i> Very burdensome for providers and surveyor Conclusion: Potential point of comparison, esp. for key drugs and markets

6.0 Recommendations and Directions for Further Work

6.1 Recommendation

There is no simple method of estimating acquisition costs. Based on our research and the comments of the Expert Panel, the authors recommend that CMS consider an approach to estimating acquisition costs that is based on collecting primary data from manufacturers. Members of the expert panel strongly favored this approach at the meeting and in their individual comments after the meeting.

In particular, in addition to list prices, manufacturers would be asked to supply average selling prices by class of trade. These classes of trade might include independent pharmacies, chain warehouses, long term care pharmacies, physicians (direct sales), and hospitals. If these data are to be used as a basis for payment under Medicare Part D which begins in January of 2006, then prices to the mail order class of trade should also be collected. Manufacturers would also be asked to note other major provider types that might be purchasing on behalf of Medicaid and Medicare beneficiaries, to explain the situation, and to provide the associated average selling prices. All terms would be carefully defined including pricing terms, as well as discounts and rebates to be included and excluded³⁶, and the channels of distribution. Manufacturers would be required to certify that the prices supplied were true and accurate.

The strengths of this approach are that it: (1) yields actual transaction prices, (2) incorporates all discounts and rebates, (3) incorporates class of trade differentials, (4) provides an efficient method (relative to a provider survey), and (5) represents a feasible approach to estimating actual acquisition cost. Similar methods are in place in the Medicaid rebate program and in the Texas Vendor Drug Program. One conceptual shortcoming of this approach is that it generates a manufacturer's sales price as opposed to a provider's acquisition cost. The authors believe that if the data are gathered by precisely defined classes of trade and channels of distribution, the manufacturers' sales costs can be accurately adjusted to produce an estimate of the providers' acquisition costs. A second practical

shortcoming is that CMS may need require new regulation or legislation in order to gather this data on a national basis from manufacturers, as they are unlikely to supply it voluntarily.

The authors also recommend that before considering additional primary data collection, CMS undertake a careful evaluation of the existing Texas Vendor Drug Program (VDP) and the price data that it collects. The Texas approach is very similar to our recommended approach. Below, we offer additional information regarding the Texas VDP, followed by a brief description of the proposed evaluation.

6.2 The Texas Vendor Drug Program

In the 1980s the Texas Vendor Drug Program studied “ways to achieve more accurate payment for the drug product portion of claims paid to pharmacy providers.”³⁷ Texas VDP recognized that the list price (AWP) in the commercial price databases was greater than the amount pharmacies actually paid the wholesaler for a drug product. The state of Texas, therefore, established statutory authority to collect the drug price information from manufacturers.

The Texas VDP set up a system to survey drug manufacturers who choose to participate in the Medicaid program. Initially each manufacturer was asked to submit a list of all drug products, at the NDC level, that it wished to have covered under the Medicaid drug program. Along with each NDC number and product description, the manufacturer was asked to provide several price points including:

- Average wholesale price;
- Price to wholesaler and/or distributor;
- Direct price to pharmacy;
- Price to chain warehouse;
- Institutional or other contract price (e.g., nursing home, home health care); and
- Other prices.

See Appendix C for examples of the standard cover letter and survey that are sent to manufacturers to request this information. The Texas VDP has also developed standard response letters to drug manufacturers for various situations (also in Appendix C).

Another important feature of the Texas price survey system is the requirement that an official of the drug company certify that the prices sent are correct. This requires the drug firm to take ownership of all price information submitted and avoids the drug firm hiding behind the wholesaler or the drug price database as the source of their prices. Also, the initial application contains a statement requiring the drug firm to report any changes in information about their products within 15 days of such change. Drug firms must report changes in formulation, product status, price or availability.

Once survey forms are received by the Texas VDP, the drug product descriptions and related price variables are entered into a single database system. This data is compared to standard price data and the manufacturer is contacted if discrepancies are observed, including cases in which the manufacturer appears to have submitted a list price in place of a market price. Even though drug firms are responsible for reporting changes in product or price information within 15 days of such a change, the Texas VDP also contacts each manufacturer annually with a copy of the product and price information on file and requests that the manufacturer review this information and make any appropriate and necessary updates.

The Texas VDP uses the data submitted by manufacturers to calculate several class of trade-specific “estimated acquisition costs” (e.g., retail-wholesale, direct, chain warehouse, nursing home). When pharmacies submit a drug claim to Texas Medicaid for payment, they include information concerning the channel of distribution through which they purchased the drug. Texas Medicaid payment is then the lowest of: (1) the AWP less a percentage; (2) WAC plus a percentage; (3) MAC, if a multiple source drug; or (4) the class of trade specific “estimated acquisition cost” reported by the manufacturer.

6.3 Directions for Further Work

The authors propose to conduct a case study of Texas’ current approach to estimating acquisition costs and to secure and analyze the data that the Texas VDP already collects from manufacturers. Such an effort could maximize the national value of what Texas is already doing. This case study could give CMS, and other states, a perspective on what would be gained from instituting such a system in other settings where the current drug product reimbursement system is based on a function of either AWP or WAC. Moreover, it could provide valuable lessons relevant to the implementation of reimbursement based on alternative price measures such as ASP.

A thorough case study would fully document the Texas VDP’s process and key stakeholders’ perceptions of the strengths and weaknesses of that process. The stakeholder analysis would might include manufacturers, wholesalers, pharmacies, other providers, and the Texas Medicaid program. Among other things, this case study would review the definitions of all pricing terms and propose definitions that would be applicable for use on a national basis. The potential value and impact of calculating prices at more detailed “class of trade” levels will be explored. The analysis would describe and evaluate the process by which the Texas VDP collects and uses the price information provided by manufacturers and converts these prices into estimated acquisition costs to determine drug product payment amounts.

In addition, the case study will analyze the costs of establishing and maintaining the Texas VDP process and price list, including data collection and analysis. Levels of staffing and skills that are necessary to support this undertaking will be determined. Finally, current and potential approaches to identifying and resolving pricing discrepancies, errors, fraud, and abuse will be examined and evaluated.

In the data analysis component, the authors would acquire the Texas VDP data and compare them to readily available price data from other sources, possibly including:

- AWP, WAC, and other list prices;
- transaction prices captured in drug market and utilization data bases, such as IMS;
- transaction prices collected via a survey of selected wholesalers;
- the maximum allowable cost (MAC) at federal and state levels for certain generics; and
- the Medicare Part B ASP (if permissible).

The comparison with the AWP and WAC is most relevant to understanding the potential savings to the Medicaid program of a new method, relative to the current methods of reimbursement. The comparison with transaction prices, either from drug market and utilization databases or from selected wholesalers, is valuable to confirm the validity of the data that Texas receives. The comparison with ASP would be highly relevant to the Medicare Part B program, especially if it emphasized potential differences by class of trade or if it emphasized potential differences between a price list that is updated continuously and a price list that is updated quarterly, with a two-quarter lag.

Based on these analyses, the authors would develop and describe insights and the best options for the implementation of a similar data collection and payment policy in another setting such as another State Medicaid program, the Medicare Part B ASP program, or a national Medicaid resource, administered by CMS. The Expert Panel might be invited to comment on initial evaluation findings and various proposals for best options. These comments could be incorporated into the final report.

Appendix A: Members of the Expert Panel

Lowell Anderson, President, Bel-Air Pharmacy

James Boyd, Senior Vice President, Network Services, Rx.com/PDX

Phil Burgess, National Director, Pharmacy Affairs, Walgreen's

Paul Deutsch, Carrier Medical Director, Empire Medicare Services Part B (NY)

Deirdre Duzor, Co-Leader, Medicaid Pharmacy Team, CMS (Also the Project Officer)

David Kreling, Professor, College of Pharmacy, University of Wisconsin

John Lockwood, Venacare

Martha McNeill, Director, Texas Medicaid/CHIP Product and Prescriber Management

Lynn Mitchell, Director, Oklahoma Medicaid

Mark Pulido, Independent, (formerly Chief Executive Officer, McKesson)

Paul Saatsoglou, Practice Leader, Global Portfolio Optimization, IMS

Bruce Stuart, Professor, School of Pharmacy, University of Maryland

Bill Sullivan, Curative Health Services

Don Thompson, Director, Center for Medicare Management, Division of Ambulatory Services, Centers for Medicare and Medicaid Services (CMS)

Robert Vito, Regional Inspector General, Office of Evaluation and Inspections, Office of the Inspector General (observer)

Richard Weininger, Oncometrix